Notice of Allowability	Application No.	Applicant(s)	
	09/693,643	SRIVASTAVA, PRAMOD K.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/28/2004*.

2. ☒ The allowed claim(s) is/are *4,9,13,17,21,25-42,44,82,83,87-91,93-106 and 109-112*.

3. ☒ The drawings filed on *20 October 2000* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Sheela Huff

Christopher Yaen
Art Unit 1643

SHEELA HUFF
PRIMARY EXAMINER

S.O.O.

EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 7/21/5005, Christine Chua requested an extension of time for 5 MONTH(S) and authorized the Director to charge Deposit Account No. 50-3013 the required fee of $2160.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1-3. (Cancelled).

4. (Previously presented) A method of treating a cancer in a subject in need of said treating comprising the steps of:

(a) administering to the subject a composition comprising a component that displays the antigenicity of a cancer cell; and

(b) administering to the subject an amount of a purified heat shock protein preparation, wherein the heat shock protein preparation comprises purified i) unbound heat shock protein, or ii) heat shock protein bound to a molecule that does not display the immunogenicity of the component.

5-8. (Cancelled).

9. (Previously presented) The method according to claim 4 wherein the heat shock protein preparation comprises a heat shock protein selected from the group consisting of hsp70, hsp90, gp96, calreticulin, and a combination of any two or more thereof.

10-12. (Cancelled).

13. (Previously presented) The method according to claim 4 wherein the heat shock protein preparation comprises purified heat shock protein bound to a molecule that does not display the immunogenicity of the component.

14-16. (Cancelled).

17. (Previously presented) The method according to claim 4 wherein the heat shock protein preparation comprises purified unbound heat shock protein.

18-20. (Cancelled).

21. (Previously presented). The method according to claim 4 wherein the heat shock protein preparation comprises heat shock protein bound to a molecule that does not display the immunogenicity of the component and purified unbound heat shock protein.

22-24. (Cancelled).

25. (Previously presented) The method according to claim 4 wherein the subject is human and the heat shock protein preparation comprises mammalian heat shock protein.

26. (Previously presented) The method according to claim 4 wherein the heat shock protein preparation is administered before the administration of the composition.

27. (Previously presented) The method according to claim 4 wherein the heat shock protein preparation is administered concurrently with the administration of the composition.

28. (Currently amended) The method according to claim 4 wherein the heat shock protein preparation is ~~preparation~~ administered after the administration of the composition.

29. (Previously presented) The method according to claim 9 wherein the heat shock protein preparation is administered before the administration of the composition.

30. (Previously presented) The method according to claim 9 wherein the heat shock protein preparation is administered concurrently with the administration of the composition.

31. (Previously presented) The method according to claim 9 wherein the heat shock protein preparation is administered after the administration of the composition.

32. (Previously presented) The method according to claim 13 wherein the heat shock protein preparation is administered before the administration of the composition.

33. (Previously presented) The method according to claim 13 wherein the heat shock protein preparation is administered concurrently with the administration of the composition.

34. (Previously presented) The method according to claim 13 wherein the heat shock protein preparation is administered after the administration of the composition.

35. (Previously presented) The method according to claim 17 wherein the heat shock protein preparation is administered before the administration of the composition.

36. (Previously presented) The method according to claim 17 wherein the heat shock protein preparation is administered concurrently with the administration of the composition.

37. (Previously presented) The method according to claim 17 wherein the heat shock protein preparation is administered after the administration of the composition.

38. (Previously presented) The method according to claim 21 wherein the heat shock protein preparation is administered before the administration of the composition.

39. (Previously presented) The method according to claim 21 wherein the heat shock protein preparation is administered concurrently with the administration of the composition.

40. (Previously presented) The method according to claim 21 wherein the heat shock protein preparation is administered after the administration of the composition.

41. (Previously presented) The method according to claim 21 wherein the heat shock protein preparation and the composition are both administered on the same day.

42. (Currently amended) The method of claim 4 or 25 wherein the ~~composition is a live vaccine, an inactivated vaccine, an attenuated vaccine, a subunit vaccine, a DNA vaccine, a RNA vaccine, or~~ component is a tumor antigen ~~vaccine~~.

43. (Cancelled).

44. (Previously presented) The method according to claim 4 wherein the cancer is selected from the group consisting of fibrosarcoma, myxosarcoma, liposarcoma, chondrosarcoma, osteogenic sarcoma, chordoma, angiosarcoma,

endotheliosarcoma, lymphangiosarcoma, lymphangioendotheliosarcoma, synovioma, mesothelioma, Ewing's tumor, leiomyosarcoma, rhabdomyosarcoma, colon carcinoma, pancreatic cancer, breast cancer, ovarian cancer, prostate cancer, squamous cell carcinoma, basal cell carcinoma, adenocarcinoma, sweat gland carcinoma, sebaceous gland carcinoma, papillary carcinoma, papillary adenocarcinomas, cystadenocarcinoma, medullary carcinoma, bronchogenic carcinoma, renal cell carcinoma, hepatoma, bile duct carcinoma, choriocarcinoma, seminoma, embryonal carcinoma, Wilms' tumor, cervical cancer, testicular tumor, lung carcinoma, small cell lung carcinoma, bladder carcinoma, epithelial carcinoma, glioma, astrocytoma, medulloblastoma, craniopharyngioma, ependymoma, pinealoma, hemangioblastoma, acoustic neuroma, oligodendroglioma, meningioma, melanoma, neuroblastoma, retinoblastoma, leukemia, acute lymphocytic leukemia, acute lymphocytic leukemia, acute myelocytic leukemia, myeloblastic leukemia, promyelocytic leukemia, myelomonocytic leukemia, monocytic leukemia, erythroleukemia leukemia, chronic leukemia, chronic myelocytic leukemia, granulocytic leukemia, chronic lymphocytic leukemia, polycythemia vera, lymphoma, Hodgkin's disease lymphoma, non-Hodgkin's disease lymphoma, multiple myeloma, Waldenström's macroglobulinemia, and heavy chain disease.

45. (Cancelled).

46-81. (Cancelled).

82. (Previously presented) The method according to claim 13 wherein the heat shock protein preparation and the composition are both administered on the same day.

83. (Previously presented) The method of claim 17 wherein the heat shock protein preparation and the composition are both administered on the same day.

84. (Cancelled).

85. (Cancelled).

86. (Cancelled).

87. (Currently amended) The method of claim 4 or 25 wherein the ~~composition~~ component is a KS 1/4 pan-carcinoma antigen [[-based vaccine]], an ovarian carcinoma antigen [[-based vaccine]], a prostatic acid phosphate [[-based vaccine]], a prostate specific antigen [[-based vaccine]], a melanoma-associated antigen p97 [[-based vaccine]], a melanoma antigen gp75 [[-based vaccine]], a high molecular weight melanoma antigen [[-based vaccine]], a MAGE family of antigens antigen [[-based vaccine]], or a prostate specific membrane antigen [[-based vaccine]].

88. (Currently amended) The method of claim 4 or 25 wherein the ~~composition~~ component is a protein subunit ~~vaccine~~.

89. (Previously presented) The method according to claim 4 or 25 wherein the heat shock protein preparation comprises a purified population of heat shock protein bound to molecules that do not display the immunogenicity of the component.

90. (Previously presented) The method according to claim 17 wherein the heat shock protein preparation comprises purified unbound heat shock proteins that are a combination of two or more heat shock proteins.

91. (Previously presented) The method according to claim 4 or 25 wherein the heat shock protein preparation comprises (a) a population of heat shock protein bound to molecules that do not display the immunogenicity of the component, and (b) purified unbound heat shock proteins.

92. (Cancelled).

93. (Previously presented) The method according to any one of claims 4, 9, 13, 17, 21, 25-41, 44, 82, or 90, wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

94. (Previously presented) The method according to claim 42 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

95. (Previously presented) The method according to claim 84 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

96. (Previously presented) The method according to claim 85 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

97. (Previously presented) The method according to claim 86 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

98. (Previously presented) The method according to claim 87 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

99. (Previously presented) The method according to claim 88 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

100. (Currently amended) The method of claim [[4 or 25]] 42 wherein the ~~composition~~ component is a tumor-associated antigen ~~vaccine~~.

101. (Currently amended) The method of claim [[4 or 25]] 42 wherein the ~~composition~~ component is a tumor specific antigen ~~vaccine~~.

102. (Previously presented) The method of claim 4 or 25 wherein heat shock protein in the heat shock protein preparation is present in an amount ranging from 0.1 µg to 1000 µg per administration.

103. (Previously presented) The method of claim 4 or 25 wherein heat shock protein in the heat shock protein preparation is gp96 or hsp70 and is present in an amount ranging from 10 µg to 600 µg per administration.

104. (Previously presented) The method of claim 4 or 25 wherein heat shock protein in the heat shock protein preparation is gp96 or hsp70, said administering is intradermal, and said heat shock protein is present in an amount ranging from 0.1 µg to 10 µg per administration.

105. (Previously presented) The method of claim 4 or 25 wherein heat shock protein in the heat shock protein preparation is hsp90 and is present in an amount ranging from 50 µg to 1000 µg per administration.

106. (Previously presented) The method of claim 4 or 25 wherein the heat shock protein in the heat shock protein preparation is hsp90, said administering is intradermal, and said heat shock protein is present in an amount ranging from 5 µg to 50 µg per administration.

107-108. (Cancelled).

109. (Previously presented) The method according to claim 89 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

110. (Previously presented) The method according to claim 91 wherein the heat shock protein preparation is administered to the subject in an amount effective to induce or increase an immune response in the subject to the component.

111. (Previously presented) The method of claim 4 or 9 wherein the heat shock protein preparation and the composition are both administered on the same day.

112. (New) The method of claim 4, 9, 25, or 44 wherein the heat shock protein preparation comprises purified heat shock protein bound to a molecule that does not display the immunogenicity of said cancer.

2. The following is an examiner's statement of reasons for allowance:

Claims of the instant invention are drawn to a method of treating cancer comprising the steps of administering to a subject a composition comprising a component that displays the antigenicity of a cancer cell, and administering to the subject an amount of a purified heat shock protein preparation. The claims have been deemed allowable over the prior art based on the arguments presented by the applicant that "heat shock protein preparation" encompasses only proteins/polypeptides and does not envisage nucleic acid molecules. Moreover, the claims are further distinguished form the prior art in that the instant method requires the administration of individual components.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

All rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 12/28/2004.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
July 21, 2005

SHEELA HUFF
PRIMARY EXAMINER